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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,978	04/25/2001	Susana Salceda	DEX-0172	3638

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EXAMINER	
HELMS, LARRY RONALD	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,978	SALCEDA ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a method of diagnosing cancer by measuring a colon specific gene. In view of this Yu et al (US Patent 5,733,748) reads on the claim. Yu et al teach a method of diagnosing cancer by measuring a colon specific gene and determining if cancer is present or metastasized (see abstract). Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:1 and the measuring is by the polynucleotide.
Group II, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:2 and the measuring is by the polynucleotide.
Group III, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:3 and the measuring is by the polynucleotide.

Group IV, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:9 and the measuring is by the polynucleotide.

Group V, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:10 and the measuring is by the polynucleotide.

Group VI, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:11 and the measuring is by the polynucleotide.

Group VII, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:12 and the measuring is by the polynucleotide.

Group VIII, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:13 and the measuring is by the polynucleotide.

Group IX, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:14 and the measuring is by the polynucleotide.

Group X, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:1 and the measuring is by the polypeptide.

Group XI, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:2 and the measuring is by the polypeptide.

Group XII, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:3 and the measuring is by the polypeptide.

Group XIII, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:9 and the measuring is by the polypeptide.

Group XIV, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:10 and the measuring is by the polypeptide.

Group XV, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:11 and the measuring is by the polypeptide.

Group XVI, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:12 and the measuring is by the polypeptide.

Group XVII, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:13 and the measuring is by the polypeptide.

Group XVIII, claim(s) 1-8 in part, drawn to methods of diagnosing, staging, monitoring cancer by measuring SEQ ID NO:14 and the measuring is by the polypeptide.

Group XIX, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:1. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XX, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:2. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXI, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:3. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXII, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:9. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXIII, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:10. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXIV, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:11. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXV, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:12. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXVI, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:13. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXVII, claim(s) 9 in part, drawn to an antibody to SEQ ID NO:14. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXVIII, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:1. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXIX, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:2. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXX, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:3. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXI, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:9. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXII, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:10. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXIII, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:11. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXIV, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:12. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXV, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:13. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXVI, claim(s) 10-11 in part, drawn to a method of imaging using an antibody to SEQ ID NO:14. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXVII, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:1. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXVIII, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:2. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXIX, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:3. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXX, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:9. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXXI, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:10. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXXII, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:11. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXXIII, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:12. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

Group XXXXIV, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:13. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.
Group XXXXV, claim(s) 12-13 in part, drawn to a method of treating a cancer using an antibody to SEQ ID NO:14. It is unclear if the antibody is against the protein product or the gene itself and this need to be clarified if this group is elected.

2. The inventions listed as Groups I-XXXXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Yu et al the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups XIX-XXVII represent separate and distinct products which bind to distinct products. The antibodies in Groups XIX-XXVII are distinct because the antibodies each bind to a distinct protein (or gene) product and an antibody binding to one would not necessarily bind to the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions XIX-XXVII are patentably distinct.

The methods of Inventions I-XVIII and XXVIII-XXXXV differ in the method objectives, method steps and parameters and in the reagents used. Inventions I-XVIII

recites a method of diagnosing, staging, monitoring cancer by measuring a distinct polypeptide or polynucleotide and each Group is distinct because each gene or polynucleotide is distinct and measuring the polynucleotide uses a nucleic acid and measuring the polypeptide uses an antibody, for example; Inventions XXVIII-XXXVII recite a method of imaging cancer by using an antibody that is to a CSG or product and each Group is distinct because the antibody is directed to a distinct protein sequence; and Inventions XXXVIII-XXXXV recites a method of treating cancer by using an antibody that is to a CSG or product and each Group is distinct because the antibody is directed to a distinct protein sequence. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I-IX and XIX-XXXVI differ in the method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions XIX-XXVII and XXVIII-XXXXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Groups XIX-XXVII can be used in a materially different methods such as to immunoprecipitate the antigen in addition to the materially different methods of Groups XXVIII-XXXXV.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached on (571) 272-0787.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the

Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832